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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,401	11/19/2003	Randall J. Huebner	ACM 354	7508

23581 7590 01/11/2006

KOLISCH HARTWELL, P.C.  
200 PACIFIC BUILDING  
520 SW YAMHILL STREET  
PORTLAND, OR 97204

EXAMINER
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RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/717,401	HUEBNER ET AL.	
	Examiner	Art Unit	
	Anu Ramana	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1, 4-31, 43, 56 and 57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 56 and 57 is/are allowed.
- 6) ☒ Claim(s) 1, 4-31 and 43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/31/05</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 4-14 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 1, lines 5-6, applicant positively recites part of a human, i.e. "guide portion is disposed across the bone from the coupling portion". Thus, claims 1 and 4-14 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

In order to overcome this rejection, it is suggested that language similar to claims 15 and 28, "configured to be disposed across the bone" be used in claim 1.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

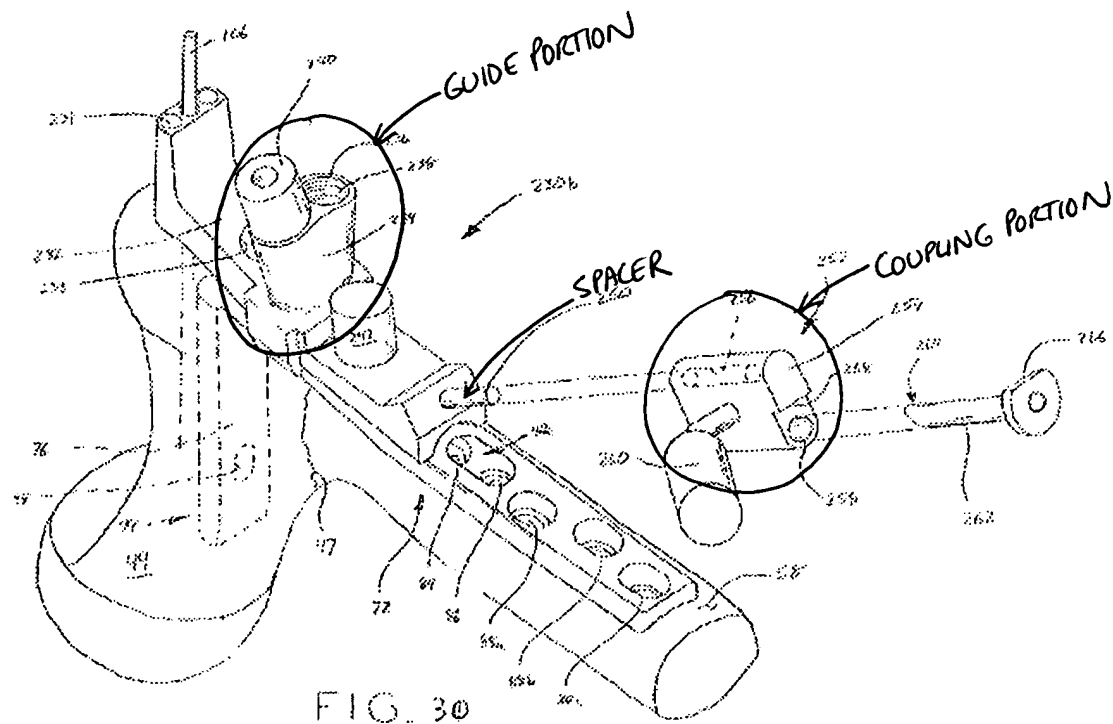
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

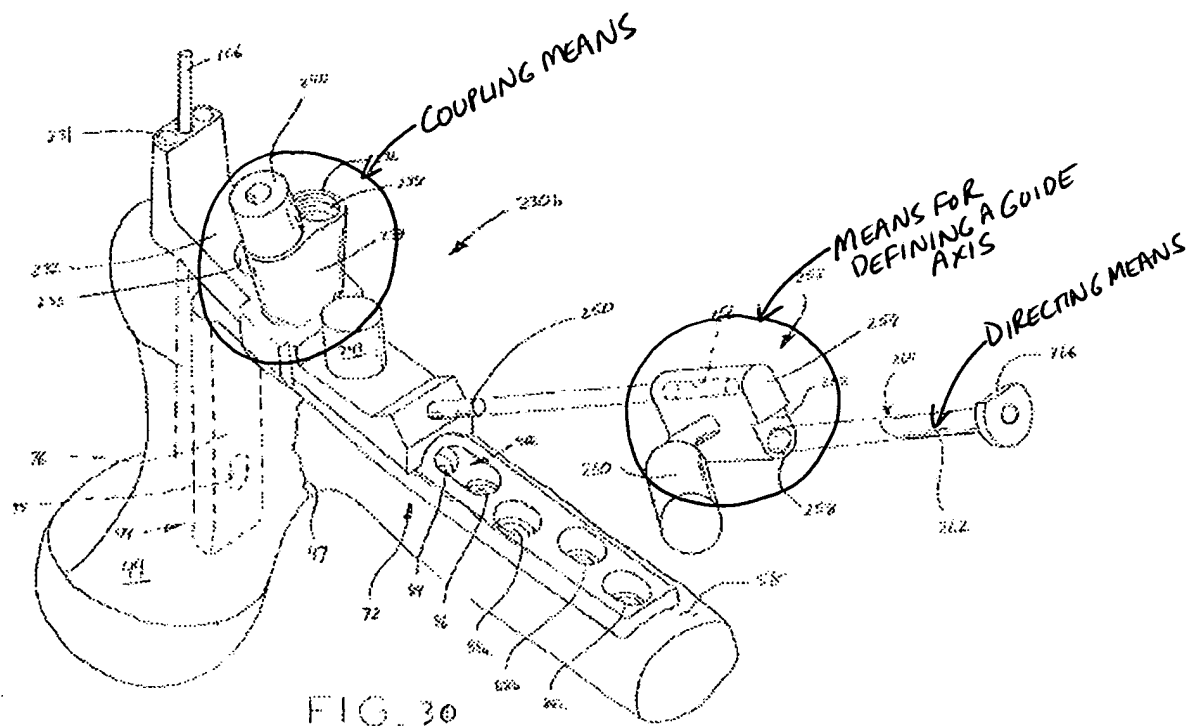
Claims 1, 4, 7-8, 10-15, 18-22, 24, 28 and 30-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Aikins et al. (US 2003/0040748).

Aikins et al. disclose a bone plate 74 with predefined positions or holes (82, 88); a guide portion 230b; a coupling portion 252 connected to the guide portion and configured to be disposed across the bone from the guide portion; a removably attached drill sleeve or cannula or guide element 240; threads or "detent mechanism" 238 in the guide portion to restrict movement of the guide element; a connective feature 98; and a spacer portion or "one additional connective feature" 250 connecting the coupling portion to the guide portion (Figs. 30-31, paras [0089]-[0092]). See marked up Figure 30 below.



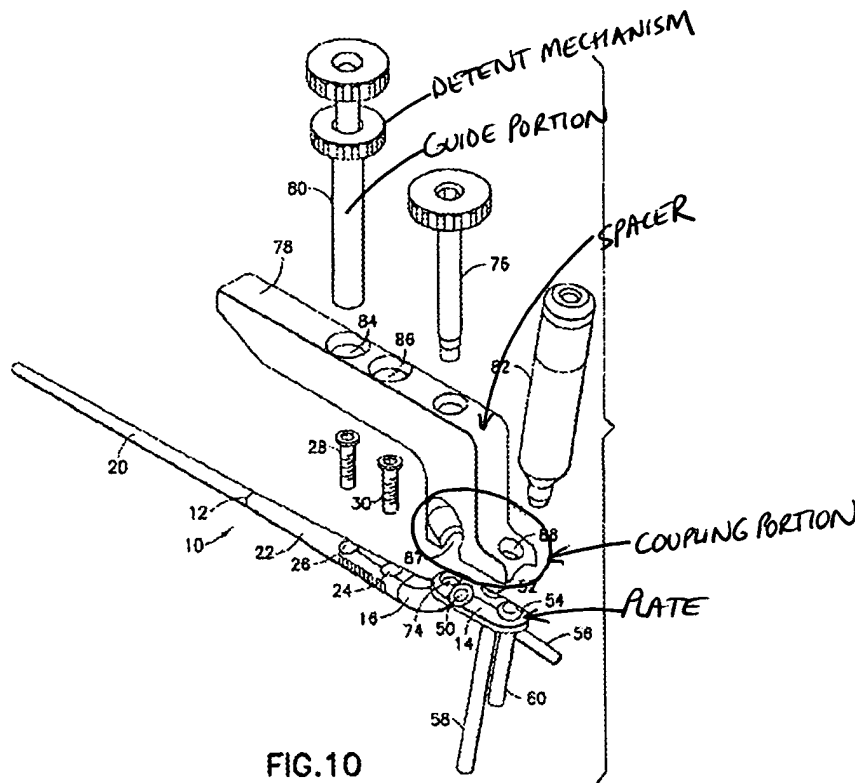
Using an alternate interpretation, claim 43 is rejected under 35 U.S.C. 102(e) as being anticipated by Aikins et al. (US 2003/0040748).

Aikins et al. disclose a bone plate 74; means for coupling to the bone plate; a means for defining a guide axis that extends through the bone (252); a means for directing a bone screw through the bone and into an opening 98 in the bone plate (Figs. 30-31, paras [0089]-[0092]). See marked up Figure 30 on the following page.



Claims 1, 5-8, 10-24, 27-28, 29-31 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Orbay et al. (US 6,706,046).

Orbay et al. disclose a device including: a coupling portion connected to a bone plate; a guide portion 80 connected to the coupling portion and configured to be disposed across the bone from the coupling portion; a plurality of connective features (24, 26, 74); and a spacer portion (Fig. 10, col. 4, lines 58-67 and col. 5, lines 1-40). See marked up Fig. 10 on the following page.



### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-6, 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aikins et al. (US 2003/0040748) in view of Talos et al. (US 5,709,686).

Aikins et al. disclose all elements of the claimed invention except for threaded openings.

Talos et al. teach providing threaded openings in a bone plate to receive a screw with a threaded head (Fig. 1 and col. 1, lines 21-45).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided threaded holes in the Aikins et al. plate, as taught by Talos et al., for receiving screws with threaded heads.

Claims 9, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aikins et al. (US 2003/0040748) in view of Cohen (US 6,540,753).

Aikins et al. disclose all elements of the claimed invention except for indicia on the guide element.

Cohen teaches providing indicia 36 on the guide shaft 40 of a drill instrument to monitor drilling depth (Fig. 1, col. 5, lines 66-67 and col. 6, lines 1-17).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided indicia, as taught by Cohen, on the guide element of Aikins et al., to monitor drilling depth for placement of a screw.

Claims 9, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orbay et al. (US 6,706,046) in view of Cohen (US 6,540,753).

Orbay et al. disclose all elements of the claimed invention except for indicia on the guide element.

Cohen teaches providing indicia 36 on the guide shaft 40 of a drill instrument to monitor drilling depth (Fig. 1, col. 5, lines 66-67 and col. 6, lines 1-17).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided indicia, as taught by Cohen, on the guide element of Orbay et al., to monitor drilling depth for placement of a screw.

### ***Response to Arguments***

Applicant's arguments submitted under "REMARKS" in the response filed on October 25, 2005 have been fully considered but are not persuasive with respect to the rejections of claims 1 and 4-31 for the following reasons.

Regarding the rejections of claims 1, 4, 7-8, 10-15, 18-22, 24, 28 and 30-31 as being anticipated by Aikins et al. it is noted that the limitation "guide portion being configured to be disposed across the bone from the coupling portion" merely requires that the guide portion be configured to be positioned on a portion of the bone surface and the coupling portion be configured to be positioned on another portion of the bone surface along a longitudinal axis of the bone. Since no axes are defined, the claims must be interpreted as broadly as their terms reasonably allow (In re Zletz, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989)).

Applicants' arguments with respect to claim 43 are moot in view of the new grounds of rejection.

#### ***Allowable Subject Matter***

Claims 56 and 57 are allowed.

#### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-




Art Unit: 3733

4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Anuradha Ramara*  
January 6, 2006

  
EDUARDO C. ROBERT  
PRIMARY EXAMINER